Order No. 276 by the State Council of the People's Republic of China

The Regulation on Supervision and Administration of Medical Devices was adopted on 28 December 1999 at the 24th regular meeting of the State Council. The Regulation is now published and will become effective on 1 April 2000.

Premier
Zhu Rongji
4 January 2000

The Regulation on Supervision and Administration of Medical Devices

Chapter 1 General Provisions

Article 1 This Regulation is hereby enacted with a view to strengthen the supervision and administration of medical devices (hereinafter referred to as D , to ensure the safety and effectiveness of MD and to protect people health and life.

Article 2 All entities or individuals that are engaged in the research and development, production, operation, application, supervision and administration activities of MD within the jurisdiction of the People Republic of China shall observe this Regulation.

Article 3 edical devices or D mentioned herein refers to any instrument, equipment, apparatus, appliance, material or other articles (including necessary software) that used alone or in combination for human bodies. The functions of MD on or in human bodies are not performed by pharmacological, immunological or metabolic means, even though the above-mentioned means may involve and play a supporting role in the performance of MD. The application of MD is intended to achieve purposes as follows:

- Prevention, diagnosis, treatment, monitoring or alleviation of diseases;
- Diagnosis, treatment, monitoring, alleviation or reparation of injuries or the handicapped;
- Research, replacement or modification of anatomy or certain physiological process;
- Control of pregnancy.

Article 4 The drug and MD administration affiliated to the State Council (hereinafter referred to as he state drag and MD administration shall be in charge of the supervision and administration of MD in China.

The drug and MD administrations affiliated to local governments above county level shall be in charge of the supervision and administration of MD in their respective administrative jurisdiction.

The state drug and MD administration shall coordinate with macro-economic regulatory departments affiliated to the State Councils to carry out the state policies on MD industry.

Article 5 The state implements administration of MD by way of classification as follows:

Class I refers to MD of which conventional management is sufficient to ensure the safety and effectiveness.

Class II refers to MD of which certain controlling measures shall be applied to ensure the safety and effectiveness.

Class III refers to MD that needs to be implanted into human bodies for life supporting and may impose potential risks on human bodies. For this category of MD, strict control shall be applied to ensure the safety and effectiveness.

Classification categories of MD shall be stipulated, published and readjusted by the state drug and MD administration in accordance with relevant provisions on MD classification, after consultations with the public health administration affiliated to the State Council.

Article 6 The production and application of MD with the purpose of providing specific magnitude shall observe relevant provisions of *Metrology Law of PRC*. The categories of such MD product shall be jointly stipulated and published by the state drug and MD administration together with the metrology administration affiliated to the State Council.

Chapter 2 Management of Medical Devices

Article 7 The state encourages research and development of new MD products. New MD product refers to totally new types of MD, which have never been seen in the domestic market or whose safety and effectiveness as well as mechanism need to be ratified by relevant authorities in China.

New MD products under class II and III may be used to clinical trials only upon the approval issued by the state drug and MD administration in accordance with relevant provisions.

New MD products that have passed clinical trials and expert assessment organized by the state drug and MD administration shall be awarded with

ew MD Product Certificate upon the approval of the state drug and MD administration.

Article 8 The state implements a registration system for the production of MD products.

The production of MD products under class I shall be examined and approved by the drug and MD administrations affiliated to governments of municipal level, and shall be conducted only upon the strength of the Registration Certificate issued by such administrations.

The production of MD products under class II shall be examined and approved by the drug and MD administrations affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government, and shall be conducted only upon the strength of Registration Certificate issued by such administrations.

The production of MD products under class III shall be examined and approved by the state drug and MD administration, and shall be conducted only upon the strength of Registration Certificate issued by such administration. The MD products under class II and class III shall be produced only after the verification by certain clinical trials.

Article 9 The drug and MD administrations affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government shall be responsible for examination and approval of the clinical trials or verifications with respect to the MD under class II within their respective administrative jurisdiction. The state drug and MD administration shall be responsible for examination and approval of the clinical trials or verifications with respect to the MD under class III.

Such clinical trials or verifications shall be conducted in the medical institutions designated by the drug and MD administrations affiliated to the governments above provincial level. The clinical trials or verifications conducted by such medical institutions shall comply with relevant provisions set by the state drug and MD administration.

The standard of medical institutions that are qualified for such clinical trials or verifications shall be stipulated jointly by the state drug and MD administration together with the public health administration affiliated to the State Council.

Article 10 Medical institutions can develop MD according to their own clinical requirements and apply such MD to patients only within the same institution under the guidance from certified doctors.

The MD under class II developed by medical institutions shall be submitted to the drug and MD administrations affiliated to the governments above provincial level for examination and approval. The MD under class III developed by medical institutions shall be submitted to the state drug and MD administration for examination and approval.

Article 11 For the MD imported to China for the first time, the import entity shall provide samples and relevant information like instruction manuals, quality specifications and testing methods, etc. and the certificates that permit the production and sales of such MD issued by their original countries (regions) to the state drug and MD administration for approval and registration. Application for import may be submitted to the customs only after the Registration Certificate for such import being obtained from the state drug and MD administration.

Article 12 In order to apply for the registration of MD, the technical specifications, test reports and other relevant information shall be submitted in accordance with relevant provisions set by the state drug and MD administration. The drug and MD administration affiliated to governments of municipal level shall determine whether to grant such registration to related MD within sixty (60) business days after the acceptance of the application. Written explanation shall be necessary in case of rejection.

The drug and MD administration affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government shall determine whether to grant such registration to related MD within sixty (60) business days after the acceptance of the application. Written explanation shall be necessary in case of rejection.

The state drug and MD administration shall determine whether to grant such registration to related MD within ninety (90) business days after the acceptance of the application. Written explanation shall be necessary in case of rejection.

Article 13 In the event that any change occurs in the content of the MD Registration Certificate, the entity holding such certificate shall apply to relevant authorities for modification or re-registration within thirty (30) days after the occurrence of such change.

Article 14 The term of validity for the Registration Certificate of MD shall be four (4) years. The entity holding such certificate may apply to relevant authorities for a renewal of registration within six (6) months prior to the expiration of such certificate.

Any Registration Certificate in relation to the MD that have stopped production for more than two (2) years shall become invalid automatically.

Article 15 The production of MD shall comply with the national standard of MD or the industry standard of MD (in the absence of the national standard).

The national standard of MD shall be stipulated jointly by the standardization administration affiliated to the State Council together with the state drug and MD administration. The industry standard of MD is to be stipulated by the state drug and MD administration.

Article 16 The instruction manuals, labels and packages of MD shall comply with relevant national standard or provisions.

Article 17 The serial number of the Registration Certificate shall be marked on the relevant MD and its external packing in accordance with the provisions set by the state drug and MD administration.

Article 18 The state implements a re-evaluation and knockout system on the MD. Detailed provisions of this system are to be stipulated by the state drug and MD administration after consultation with relevant authorities affiliated to the State Council.

Chapter 3
Management of Production, Business Operation and Application of MD

Article 19 Production enterprises of MD products shall satisfy conditions as follows:

1. With qualified professional technicians for MD production;

2. With qualified site and environment for MD production;

3. With qualified equipment for MD production;

4. With qualified institutions or personnel as well as relevant equipment to carry out quality inspection for the produced MD products.

Article 20 The incorporation of production enterprises for MD products under class I shall be reported to the drug and MD administrations affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government for filing.

The incorporation of production enterprises for MD products under class II and III shall be examined and approved by the drug and MD administrations affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government. A Production License for MD shall be granted to qualified enterprises upon the approval. The administrations of industry and commerce may not issue any business license to the production enterprises without such Production License.

The term of validity for such Production License shall be five (5) years. Production enterprises for MD shall receive re-examination and apply for new Production License upon expiration. Detailed provisions are to be stipulated by the state drug and MD administration.

Article 21 Production enterprises for MD may not star production before the Registration Certificate for MD production being granted to such enterprises.

Article 22 The state implements a mandatory safety certification system for certain MD under class III. Detailed categories of such MD product are to be stipulated jointly by the state drug and MD administration together with quality supervisory authorities affiliated to the State Council.

Article 23 Enterprises engaged in MD businesses shall satisfy conditions as follows:

1. With qualified site and environment for MD businesses;

2. With qualified personnel to carry out quality inspection for the produced MD;

3. With capacity to provide after-sales services like technical training and maintenance in relation with relevant MD products.

Article 24 The incorporation of enterprises engaged in businesses of MD products under class I shall be reported to the drug and MD administration affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government for filing.

The incorporation of enterprises engaged in businesses of MD products under class II and class III shall be examined and approved by the drug and MD administrations affiliated to the governments of relevant provinces, autonomous regions and municipalities directly under the central government. An Operation License for MD businesses shall be granted to qualified enterprises upon the approval. The administrations of industry and commerce may not issue any business license to the enterprises without such Operation License.

The term of validity for such Operation License shall be five (5) years. Enterprises engaged in businesses of MD products shall receive re-examination and apply for new Operation License upon expiration. Detailed provisions are to be stipulated by the state drug and MD administration.

Article 25 The drug and MD administrations affiliated to the governments of relevant provinces, autonomous region and municipalities directly under the central government shall determine whether to grant the Production License for MD or the Operation License for MD businesses within thirty (30) business days after the acceptance of the application. Written explanation shall be necessary in case of rejection.

Article 26 Enterprises engaged in MD businesses and medical institutions shall purchase qualified MD from production enterprises of MD with the Production License or enterprises engaged in MD businesses with the Operation License, and shall at the same time check their certificate of quality.

The said enterprises of MD businesses shall not engage in business of the MD that have not been registered, have no certificate of quality, have lost efficacy, or have become expired or outmoded.

The medical institutions shall not use the MD that have not been registered, have no certificate of quality, have lost efficacy, or have become expired or outmoded.

Article 27 The medical institutions shall not reuse disposable MD. The used MD shall be destroyed and recorded by the medical institutions according to relevant provisions of the state.

Article 28 The state has established a reporting system and a publication system for accidents caused by MD with poor quality. Detailed provisions of these systems are to be jointly stipulated by the state drug and MD administration together with the public health administration and family planning administration affiliated to the State Council.

Chapter 4 Supervision of MD

Article 29 The drug and MD administration affiliated to the governments above county level shall have their MD supervisors. The MD supervisors shall supervise and inspect the production enterprises of MD, the enterprises engaged in MD businesses and the medical institutions within their respective administrative jurisdiction; they may draw samples and ask for relevant materials according to the provisions set by the state drug and MD administration when necessary. Entities and individuals concerned shall not refuse to provide such samples and materials or withhold the facts. The MD supervisors shall assume the obligations to keep such samples and materials confidential.

Article 30 The state implements a certification system for the qualifications of testing institutions of MD. Only the testing institutions certified jointly by the state drug and MD administration and the quality supervisory authorities affiliated to the State Council are qualified to carry out tests for MD.

The testing institutions of MD and their staffs shall assume the obligations to keep the technical materials of the tested entities confidential, and shall not engage in or participate in activities such as research and development, production, operation and technical consultation in relation to the tested MD.

Article 31 The drug and MD administrations affiliated to the governments above county level may seal up or detain the MD (and relevant data) that have caused or may cause accidents due to the poor quality of such MD.

Article 32 The drug and MD administration affiliated to the governments above provincial level shall revoke the Registration Certificate of the MD product if the safety and effectiveness of such MD cannot be guaranteed.

The MD with the Registration Certificate being revoked shall not be produced, sold and applied to patients. The drug and MD administration affiliated to the governments above county level shall be responsible to treat any unqualified MD that has been produced or imported.

Article 33 In the event that the drug and MD administrations affiliated to the governments above municipal level wrongly grant Registration Certificate and breach the provisions of the Regulation, the state drug and MD administration shall order them to correct their mistakes within the specified time. If such administrations fail to correct their mistakes within the specified time, the state drug and MD administration can make a public announcement to revoke the unlawful Registration Certificate of MD.

Article 34 Advertisements of MD shall be examined and approved by the drug and MD administrations affiliated to the governments above provincial level. The Advertisements without such approval may not be published, broadcast, circulated and posted.

The content of MD advertisements shall be strictly in compliance with the relevant instruction manuals approved by the state drug and MD administration or the drug and MD administrations affiliated to the governments of relevant provinces, autonomous region and municipalities directly under the central government.

Chapter 5 Penalties

Article 35 In the event that any enterprise or individual violates the provisions of the Regulation and produces MD products in the absence of Registration Certificate for MD production, the drug and MD administrations affiliated to governments above county level shall order relevant enterprises or individuals to stop such illegal production, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 10 thousand, administrations concerned shall additionally impose a fine being equivalent to 3 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 10 thousand, administrations concerned shall impose a fine of RMB 10 to 30 thousand. For cases with a serious nature, the drug and MD administrations affiliated to the governments of relevant provinces, autonomous region and municipalities directly under the central government shall revoke the Production License of MD; for cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 36 In the event that any enterprise or individual violates the provisions of the Regulation and produces MD products under class II and III in the absence of the Production License of MD, the drug and MD

administrations affiliated to governments above county level shall order relevant enterprises or individuals to stop such illegal production, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 10 thousand, administrations concerned shall additionally impose a fine being equivalent to 3 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 10 thousand, administrations concerned shall impose a fine of RMB 10 to 30 thousand. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 37 In the event that any enterprise or individual violates the provisions of the Regulation and produces MD products at variance with national standard and industry standard of MD, the drug and MD administrations affiliated to governments above county level shall give a warning, order relevant enterprises or individuals to stop such illegal production, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 5 thousand, administrations concerned shall additionally impose a fine being equivalent to 2 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 5 thousand, administrations concerned shall impose a fine of RMB 5 to 20 thousand. For cases with a serious nature, the administration concerned shall revoke the Registration Certificate of MD; for cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 38 In the event that any enterprise or individual violates the provisions of the Regulation and engages in businesses of MD products under class II and III in the absence of the Operation License of MD, the drug and MD administrations affiliated to governments above county level shall order relevant enterprises or individuals to stop such illegal operation, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 5 thousand, administrations concerned shall additionally impose a fine being equivalent to 2 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 5 thousand, administrations concerned shall impose a fine of RMB 5 to 20 thousand. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 39 In the event that any enterprise or individual violates the provisions of the Regulation and engages in business of the MD that have not been registered, have no certificate of quality, have lost efficacy, or have become expired or outmoded, or purchases MD from the enterprises without the Production License or the Operation License, the drug and MD administrations affiliated to governments above county level shall give a warning, order relevant enterprises or individuals to stop such illegal operation, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 5 thousand, administrations concerned shall additionally impose a fine being equivalent to 2 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 5 thousand,

administrations concerned shall impose a fine of RMB 5 to 20 thousand. For cases with a serious nature, the administration concerned shall revoke the Operation License of MD; for cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 40 In the event that any enterprise or individual violates the provisions of the Regulation and provides false certificates, documents and samples when applying for registration of MD, or attempt to obtain the Registration Certificate of MD by other means of deceit, the original registration authorities shall revoke the Registration Certificate of MD and shall not accept any application for registration from such enterprises or individuals within two years. In addition, administrations concerned shall impose a fine of RMB 10 to 30 thousand. For enterprises that have started operation, administrations concerned shall confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 10 thousand, administrations concerned shall additionally impose a fine being equivalent to 3 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 10 thousand, administrations concerned shall impose a fine of RMB 10 to 30 thousand. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 41 In the event that any enterprise or individual violates the provisions of Article 34 under this Regulation on MD advertisements, the relevant administrations of industry and commerce shall be responsible to handle the issue according to laws and regulations.

Article 42 In the event that any medical institution violates the provisions of the Regulation and use the MD that have not been registered, have no certificate of quality, have lost efficacy, or have become expired or outmoded, or purchases MD from the enterprises without the Production License or the Operation License, the drug and MD administrations affiliated to governments above county level shall give a warning, order relevant institutions to correct their mistakes, and confiscate all the illegal products and unlawful incomes. If the unlawful income exceeds RMB 5 thousand, administrations concerned shall additionally impose a fine being equivalent to 2 to 5 times of such unlawful income; if there is no such unlawful income or the unlawful income is less than RMB 5 thousand, administrations concerned shall impose a fine of RMB 5 to 20 thousand. Authorities concerned shall give persons who take charge of relevant medical institutions and persons who are directly responsible for such mistakes disciplinary punishment. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 43 In the event that any medical institution violates the provisions of the Regulation by reusing disposable MD products and keep the MD that should have been destroyed, the drug and MD administrations affiliated to governments above county level shall give a warning, order relevant institutions to correct their mistakes, and impose a fine of RMB 5 to 30

thousand. For cases with a serious nature, administrations concerned can impose a fine of RMB 30 to 50 thousand. Authorities concerned shall give persons who take charge of relevant medical institution and persons who are directly responsible for such mistakes disciplinary punishment. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 44 In the event that any medical institution that assume the responsibility to carry out clinical trials or verifications violates the provisions of the Regulation by providing false report on such trials or verifications on MD, the drug and MD administrations affiliated to governments above the provincial level shall give a warning, order relevant institutions to correct their mistakes, and impose a fine of RMB 10 to 30 thousand. For cases with a serious nature, administrations concerned can revoke the qualification of such medical institutions to carry out clinical trials or verifications. Authorities concerned shall give persons who take charge of relevant medical institutions and persons who are directly responsible for such mistakes disciplinary punishment. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 45 In the event that the testing institutions of MD and their staffs violates the provisions of the Regulation by engaging in or participating in activities such as research and development, production, operation and technical consultation in relation to the tested MD, or by providing false test report, the drug and MD administrations affiliated to governments above provincial level shall give a warning, order relevant institutions to correct their mistakes, and impose a fine of RMB 10 to 30 thousand. For cases with a serious nature, the state drug and MD administration can revoke the qualification of such testing institutions to carry out tests on MD. Authorities concerned shall give persons who take charge of relevant testing institution and persons who are directly responsible for such mistakes disciplinary punishment. For cases that constitute a crime, persons concerned shall be prosecuted for its criminal liability.

Article 46 In the event that any supervision and management staff of MD violates the provisions of the Regulation by abusing their powers, playing favoritism, committing irregularities and ignoring their duties and constitutes a crime, persons concerned shall be prosecuted for its criminal liability. For cases that do not constitute a crime, persons concerned shall be sanctioned by disciplinary punishment.

Chapter 6 Supplementary Provisions

Article 47 Management provisions on non-profitable contraception devices are to be stipulated separately by the state drug and MD administration and other relevant departments affiliated to the State Council.

Article 48 This Regulation is to become effective on 1 April 2000.